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Risk based auditing-Developing a quality assurance audit strategy and execution plan that mitigates risk and optimizes resources

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Risk Ready', a phrase that is catching up quickly within the pharmaceutical and biotechnology research space; it's not just a buzz word that's in fashion, but an essential thought that dominates all aspects of research. It is equally applicable to the Quality Assurance part overseeing such a research process. For instance; the pace and level of outsourcing has continued to evolve and now includes all business areas. Outsourcing decisions often occur under the radar focusing on the economics of the agreement and not risk management oversight. In these scenarios, it is quite common to perform a risk assessment after a contract has been signed leaving a company with very little leverage to address critical audit findings. Risk assessments should be performed before the contracts are signed so that the requirement to correct critical findings makes its way into the contract between the parties. Risk Based Auditing (RBA) is an audit process that explains how risk concepts are integrated into strategies and approaches used for management systems. RBA provides: Mechanism for understanding specific risks which may influence achievement of company objectives, description of existing measures and proposed strategies for managing specific risks, mechanism for monitoring, performing internal auditing and reporting practices and procedures. RBA changes the way internal auditors think and talk about risk. Instead of focusing on history, audit reports address the present and organization's level of preparedness to deal with the future. RBA places an emphasis on risk-based internal audit reports rather than on traditional controls-based reports.

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